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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,201	11/08/2000	William M. Mitchell	50150/007002	4075

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/709,201	Applicant(s) MITCHELL ET AL.	
	Examiner Ja-Na A Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 November 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48 and 68-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *48 and 68-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Sequence Requirement

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

    1. Claim 48 and 68-73 is drawn to a method of detecting *Chlamydia*, comprising on the sample an antigen capture assay using an antibody that specifically binds to a peptide having a sequence of SEQ ID NO:93, classified in class 435, subclass 7.36.
    2. Claim 74 is drawn to a substantially pure polypeptide consisting essentially of SEQ ID NO:93, classified in class 424, subclass 263.1.
    3. Claim 75 is drawn to an antibody that binds a peptide having a sequence consisting of essentially SEQ ID NO: 93, classified in class 530, subclass 389.5.
    4. Claim 48 and 68-73 is drawn to a method of detecting *Chlamydia*, comprising on the sample an antigen capture assay using an antibody that specifically binds to a peptide having a sequence of SEQ ID NO:96, classified in class 435, subclass 7.36.
    5. Claim 74 is drawn to a substantially pure polypeptide consisting essentially of SEQ ID NO:96, classified in class 424, subclass 263.1.
    6. Claim 75 is drawn to an antibody that binds a peptide having a sequence consisting of essentially SEQ ID NO: 96, classified in class 530, subclass 389.5.

7. Claim 48 and 68-73 is drawn to a method of detecting *Chlamydia*, comprising on the sample an antigen capture assay using an antibody that specifically binds to a peptide having a sequence of SEQ ID NO:97, classified in class 435, subclass 7.36.

8. Claim 74 is drawn to a substantially pure polypeptide consisting essentially of SEQ ID NO:97, classified in class 424, subclass 263.1.

9. Claim 75 is drawn to an antibody that binds a peptide having a sequence consisting of essentially SEQ ID NO: 97, classified in class 530, subclass 389.5.

10. Claim 48 and 68-73 is drawn to a method of detecting *Chlamydia*, comprising on the sample an antigen capture assay using an antibody that specifically binds to a peptide having a sequence of SEQ ID NO:100, classified in class 435, subclass 7.36.

11. Claim 74 is drawn to a substantially pure polypeptide consisting essentially of SEQ ID NO:100, classified in class 424, subclass 263.1.

12. Claim 75 is drawn to an antibody that binds a peptide having a sequence consisting of essentially SEQ ID NO: 100, classified in class 530, subclass 389.5.

13. Claim 48 and 68-73 is drawn to a method of detecting *Chlamydia*, comprising on the sample an antigen capture assay using an antibody that specifically binds to a peptide having a sequence of SEQ ID NO:101, classified in class 435, subclass 7.36.

14. Claim 74 is drawn to a substantially pure polypeptide consisting essentially of SEQ ID NO:101, classified in class 424, subclass 263.1.

15. Claim 75 is drawn to an antibody that binds a peptide having a sequence consisting of essentially SEQ ID NO: 101, classified in class 530, subclass 389.5.

2. The inventions are distinct, each from the other because of the following reasons:

3. As to Groups 1, 4, 7, 10, and 13, the groups are drawn to a method of detecting *Chlamydia*, comprising on the sample an antigen capture assay using an antibody that specifically binds to a peptide having a sequence selected from SEQ ID NO: 93, 96, 97, 100, 101. The inventions are distinct, each from the other because of the following reasons: The methods rely upon the products of the peptides selected from SEQ ID NO: 93, 96, 97, 100 and 101 which are distinct physically, structurally, and functionally; and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct amino acid sequences which do not share a substantial structural feature disclosed as being essential to the utility of the invention.

As to Groups 2, 5, 8, 11 and 14 the groups are drawn substantially pure polypeptides having different sequences selected from SEQ ID NO: 93, 96, 97, 100, 101. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions

for the following reasons: these products appear to constitute patentably distinct inventions for the following reasons: the numbered groups are directed to substantially pure polypeptides having a sequence consisting of essentially of SEQ ID NO: 93, 96, 97, 100 and 101 which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct amino acid sequences which do not share a substantial structural feature disclosed as being essential to the utility of the invention.

As to Groups 3, 6, 9, 12 and 15, the groups are drawn to antibodies that bind peptides having different sequences selected from SEQ ID NO: 93, 96, 97, 100, 101. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: the numbered groups are directed to antibodies that bind to one of the peptides of SEQ ID NO: 93, 96, 97, 100 and 101 that are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct amino acid sequences which do not share a substantial structural feature disclosed as being essential to the utility of the invention.

4. Inventions directed to the method of detection (groups 1 ,4, 7, 10 and 13) and the polypeptides (groups 2, 5, 8, 11, and 14) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of detection does not use the polypeptide product, but rather an antibody. Therefore the polypeptides can be used in different processes of use, such as in a method to produce antibodies. Therefore, the polypeptide product as claimed can be used in a materially different process of using that product.

5. Inventions directed to the method of detection (groups 1 ,4, 7, 10 and 13) and the antibodies (groups 3, 6, 9, 12 and 15) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies can be practiced with different processes of use; such as using the antibodies in methods of purifying an antigen using affinity chromatography techniques. Because the antibody could be used in different methods of use each product is separate. Therefore, the antibody product can be used in a materially different process of using that product.

6. Inventions directed to polypeptides (groups 2, 5, 8, 11, and 14) and antibodies (groups 3, 6, 9, 12 and 15) are unrelated. Inventions are unrelated if it can be shown

that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. The polypeptides and antibodies are drawn to different products. The antibody has different functions, such as being used in methods of detecting Chlamydia, whereas the polypeptide is not useful in said methods. The inventions have different structures and provide for different effects. Therefore, the inventions are unrelated since they have different modes of operation, functions and effects.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by theirdivergent subject matter, and because they require non-co-extensive searches, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

10. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. See attached papers.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na A Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
April 18, 2002

PATRICIA A. DUFFY
PRIMARY EXAMINER